For background information, please see CL 2024/53-FL

Codex Members and Observers are invited to submit general and specific comments on the revision to the *general standard for the labelling of prepackaged foods* (CXS 1-1985) (GSLPF) (Appendix I) relevant to allergen labelling and annex to the GSLPF: (Appendix II)below.

Comments are invited to:

i) the revision to the GSLPF (Appendix I), in particular:

   a. definition of 'food allergen' – two draft definitions are provided in Appendix II for CCFL consideration.

   b. section 4.2.1.6 – Exemptions in relation to the scientific advice and proposed alternate text, and whether to provide a list of exemptions in the GSLPF (or elsewhere), or alternatively to reference the 'current accepted exemptions' as examples.

   c. section 4.2.1.7 – Sulphite and proposed revised text which includes the option of 'food as offered to the consumer' and 'food as consumed'.

   d. section 8.3 – Declaration of certain foods and ingredients and specifically the proposed revised text for sections 8.3.1, 8.3.2 and 8.3.2.1.

   e. whether the text is ready for advancement to Step 8.

ii) the guidelines on the use of PAL (Appendix II), in particular:

   a. purpose section in regard to determining if and how PAL thresholds can address cross contact from gluten containing cereals for consumers with coeliac disease.

   b. principle 4.2 in regard to proposed alternative text on the types of risk assessment.

   c. principle 4.3 and the table of reference doses in 4.3.1 particularly in relation to inclusion of gluten.

   d. whether the text is ready for advancement to Step 5.

iii) whether to provide further advice to CCFH to ensure consistency of the *Code of Practice on Allergen Management for Food Business Operators* (CXC 80-2020) with the revision to the GSLPF and the guidelines on the use of PAL.

APPENDIX I

PROPOSED DRAFT REVISION OF THE *GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS* (CXS 1-1985) RELEVANT TO ALLERGEN LABELLING

(revisions to GSLPF are presented as **bolded** additions and ~~strikethrough~~ deletions)

2. DEFINITION OF TERMS

"Food allergy" means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food.

"Food allergen" means a food or ingredient ~~[or substance or processing aid]~~ **including a food additive or processing aid** usually **containing** a protein or protein derivative, that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.

OR

"Food Allergen" **means a food (including ingredients, food additives and processing aids) that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals, usually caused by a protein or protein derivative in the food.**

"Coeliac disease" means a chronic immune-mediated intestinal disease in genetically predisposed individuals induced by exposure to dietary gluten proteins that come from wheat, rye, barley and triticale (a cross between wheat and rye).

4. MANDATORY LABELLING OF PREPACKAGED FOODS

4.2 List of ingredients

4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, the ingredients need not be declared, except for the foods and ingredients listed in section 4.2.1.4, 4.2.1.7 and where applicable section 4.2.1.5 and food additives which serve a technological function in the finished product.

4.2.1.4 The following foods and ingredients are known to trigger food allergy or coeliac disease and shall always be declared using the specified name in addition to or as part of the ingredient name[1]:

FOODS AND INGREDIENTS	SPECIFIED NAME
Cereals containing gluten[2] − wheat and other *Triticum* species − rye and other *Secale* species − barley and other *Hordeum* species and products thereof	 'wheat' 'rye' 'barley'
Crustacea and products thereof	'crustacea'
Eggs and products thereof	'egg'
Fish and products thereof	'fish'
Peanuts and products thereof	'peanut'
Milk and products thereof	'milk'
Sesame and products thereof	'sesame'
Specific tree nuts − Almond (***Prunus amygdalus***)	 'almond'

[1] In accordance with Section 4.1.1 of the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985), the ingredient declaration should specify the true nature of the food and be specific and not generic.

[2] Includes spelt, Khorasan, and other specific cereals containing gluten that are species or hybridized strains under the genus names of *Triticum*, *Secale* and *Hordeum*. Specified names are to be used according to the associated genus. Hybridized strains are to use specified names in conjunction from all of the parent genera (e.g. 'wheat' and 'rye' for triticale).

Commented [EFOAAADPA1]: Comment (358) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:35)
EFA prefers this first option, as it is simpler and more readable.

Commented [EFOAAADPA2]: Comment (359) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:36)
EFA agrees with the addition of genus names for tree nuts, and encourages the same labelling type to apply for PAL too.

− Cashew (***Anacardium occidentale***)	'cashew'
− Hazelnut (***Corylus spp***.)	'hazelnut'
− Pecan (***Carya illinoinensis***)	'pecan'
− pistachio (***Pistacia vera***)	'pistachio'
− walnut (***Juglans spp.***)	'walnut'
and products thereof	

4.2.1.5 In addition to the foods and ingredients listed in section 4.2.1.4, the declaration of any other foods and ingredients, including those listed below may also be required[3] using a specified name in addition to or as part of the ingredient name[4]. This shall be based on available risk assessment data for the respective population(s)[5] taking into account risk management considerations.

FOODS AND INGREDIENTS	**SPECIFIED NAME**
Buckwheat and products thereof	'buckwheat'
Celery and products thereof	'celery'
Oats and other *Avena* species (and their hybridized strains) and products thereof[6]	'oats'
Lupin and products thereof	'lupin'
Mustard and products thereof	'mustard'
Soybean and products thereof	'soy'
Specific tree nuts − Brazil nut (***Bertholletia excelsa***) − macadamia (***Macadamia integrifolia, Macadamia tetraphylla***) − pine nut (***Pinus spp.***) and products thereof	'Brazil nut' 'macadamia' 'pine nut'

4.2.1.6 Subject to evaluation using established criteria[7], regional or national authorities may exempt ingredients derived from foods listed in section 4.2.1.4, and where applicable section 4.2.1.5, from being declared.

4.2.1.7 Sulphite when present in concentrations of 10 mg/kg or more[8] in a food [as offered to the consumer/as consumed] shall always be declared using the specified name 'sulphite' or 'sulfite' in addition to or as part of the ingredient name.

RENUMBER existing sections 4.2.1.5 and 4.2.1.6 to 4.2.1.8 and 4.2.1.9 respectively.

4.2.2 The presence in any food or food ingredients obtained through biotechnology of ~~a~~ **food** allergen transferred from any of the foods and ingredients listed in sections 4.2.1.4 and where applicable 4.2.1.5 shall be declared.

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3 These foods and ingredients are not included in 4.2.1.4 but have been recommended to be considered for risk management at the regional or national level (see FAO and WHO Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment https://doi.org/10.4060/cb9070en.).

4 In accordance with Section 4.1.1 of the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985), the ingredient declaration should specify the true nature of the food and be specific and not generic.

5 The assessment of risk in the respective population(s) to be based on the evidence criteria of prevalence, potency and severity of immune mediated adverse reactions to the food or ingredient as established by FAO and WHO Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment. https://doi.org/10.4060/cb9070en

6 Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore, the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level.

7 **FAO and WHO (2024). Risk assessment of food allergens: Part 4: Establishing exemptions from mandatory declaration for priority food allergens https://doi.org/10.4060/cc9554en**

8 **Sulphite measured as the total concentration of sulphur dioxide (SO_2) and sulphur dioxide equivalents.**

Commented [EFOAAADPA3]: Comment (360) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:36)
EFA agrees with the addition of genus names for tree nuts, and encourages the same labelling type to apply for PAL too.

Commented [EFOAAADPA4]: Comment (361) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:38)
EFA agrees with the wording of 4.2.1.6 as proposed. Furthermore, we support providing a list of exemptions in the GSLPF, based on the scientific advice arising from the relevant FAO/WHO report of 2024 (https://www.who.int/publications/i/item/9789240088924 4). This could be done by way of a table.

Meanwhile, EFA reminds that beer should be removed from the list of exemptions (provided in Australia and New Zealand) due to its high content in wheat, barley and gluten.

Moreover, we would like to highlight that there are at least two current exemptions that are not listed in this table:
• Lactitol (exempted in the EU and Argentina)
• Refined oils (exempted in the USA), including refined fish oil e.g. DHA and other oils (except cold pressed oils).

Overall, EFA strongly believes that applying exemptions must not lead to a potential harm to food allergy patients. At the same time, unnecessary restrictions on food choices often leads consumers with food allergy to develop clinical anxiety towards their available food options.

Commented [EFOAAADPA5]: Comment (362) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:39)
Regarding the additional text 'as offered to the consumer/as consumed', at EFA we believe that sulphite in concentrations of 10mg/kg or more should be declared in both cases: as offered to the consumer AND as consumed i.e. following preparation before consuming at home.

When it is not possible to provide adequate information on the presence of these **food** allergens through labelling, the food containing the **food** allergen should not be marketed.

4.2.3 Except for those foods and ingredients **as** listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 **that must be declared using the specified name in addition to or as part of the ingredient name,** ~~a specific name shall be used for~~ ingredients in the list of ingredients **shall be declared** in accordance with the provisions set out in Section 4.1 (Name of the Food) except that:

4.2.3.1 Unless a general class name would be more informative, the following class names may be used. ~~In all cases, the food and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared using the specified names listed in those sections~~. **When a class name is used for foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared using the specified name in addition to or as part of the class name.**

4.2.4 Processing aids and carry-over of food additives.

4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids that contain the foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5.

6. EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS

With the exception of spices and herbs, small units, where the largest surface area is less than 10 cm², may be exempted from the requirements of paragraphs 4.2 and 4.6 to 4.8. This exemption does not apply to the declaration of foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5.

8. PRESENTATION OF MANDATORY INFORMATION

8.3 Declaration of certain foods and ingredients

8.3.1 The specified name for the foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared so as to contrast distinctly from the surrounding text such as through the use of font type, style or colour.

8.3.2 The specified name for the foods and ingredients in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared in the list of ingredients or in a separate statement or in both.

8.3.2.1 If used the separate statement shall commence with the word 'Contains' (or equivalent word) and be placed directly under or in close proximity to the list of ingredients when present.

8.3.3 Where a food is exempt from declaring a list of ingredients, the foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared, such as in a separate statement made in accordance with section 8.3.2.1.

8.3.4 For single ingredient foods, section 8.3.3 does not apply where foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 are declared as part of, or in conjunction with, the name of the food.

Commented [EFOAAADPA6]: Comment (363) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:40)
We identify two slight inaccuracies in this section:
1) In the first sentence, the note that 'the following class names may be used' gives the impression that the list of class names will follow, yet it does not.
2) In the second sentence the subject is missing. Perhaps the right version would be the following:
'When a class name is used for foods and ingredients listed in ....., THESE FOODS AND INGREDIENTS shall be declared using the specific name in addition to or as part of the class name'

Commented [EFOAAADPA7]: Comment (364) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:40)
EFA fully agrees with the proposed revised text.

Commented [EFOAAADPA8]: Comment (365) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:41)
EFA takes positive note that the declaration of mandatory information (regarding whether it will be in the list of ingredients, in a separate statement, or both) is not left at the discretion of national competent authorities.

However, we insist that separate allergen statements must be mandatory, as a practice that would benefit all consumers combining convenience, exhaustiveness and standardisation. For EFA, this would materialise through a dedicated 'Allergen Statement', containing all relevant information related to allergens, including PAL.

Therefore, we propose the text to be revised as follows:
''The specified name for the foods and ingredients in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared in a separate statement or in both the list of ingredients and in a separate statement.''

Commented [EFOAAADPA9]: Comment (366) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:41)
EFA firmly believes that that the separate statement on allergens must be single, consistent, and easy to find.

In line with the previous consultation, EFA strongly urges for the removal of '(or equivalent word)', considering that the harmonised use of a single word such as 'Contains' provides for safety and equal implementation.

Moreover, we reiterate that the separate statement should be placed 'directly under' to the list of ingredients, and therefore the text 'in close proximity to' must be removed from the revised version. We consider that 'in close proximity' is too vague and might prove difficult in cases of big packaging.

In this light, and in line with our long-standing support in ...

Commented [EFOAAADPA10]: Comment (367) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:41)
Given EFA's support for a mandatory, single and consistent 'Allergen Statement', EFA calls for the removal of 'such as', as it introduces potential statements that can create confusion among consumers.

APPENDIX II

PROPOSED DRAFT ANNEX TO THE GSLPF:

GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING

1. PURPOSE

To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with food allergy[1] **or coeliac disease** about the risk from the unintended presence of allergens in food due to cross-contact.

2. SCOPE

These guidelines apply to PAL when used to indicate the risk from the unintended presence of a food allergen(s) caused by cross-contact in prepackaged[2] foods.

3. DEFINITION *OF PRECAUTIONARY ALLERGEN LABELLING*

For the purpose of these guidelines:

"Precautionary allergen labelling" *is a statement made in the labelling of prepackaged foods to indicate a risk from the unintended presence of a food allergen(s)[3] due to cross-contact[4] that has been identified by a risk assessment..*

4. GENERAL PRINCIPLES

4.1 Effective allergen management practices including controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented in accordance with the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of a food allergen(s) cannot be prevented or controlled using these allergen management practices and may result in an exposure above a reference dose.

4.2 The decision to use PAL shall be based on the findings of a risk assessment[5] of unintended allergen presence to determine potential exposure above a reference dose.

4.3 PAL shall only be used if unintended allergen presence cannot be mitigated to a level at or below the action level[6] for a food allergen based on the reference doses in the table at 4.3.1.

4.3.1 References doses

	Reference dose (RfD) **(mg total protein from the allergen)**
Almond	1.0
Brazil nut	1.0
Cashew (and Pistachio)	1.0
Macadamia	1.0
Pine nut	1.0
Walnut (and Pecan)	1.0
Celery	1.0
Mustard	1.0
Peanut	2.0

1 As defined in the *General Standard for the Labelling of Prepackaged Foods (CXS 1-1985)*
2 As defined in the *General Standard for the Labelling of Prepackaged Foods (CXS 1-1985)*
3 As defined in the *General Standard for the Labelling of Prepackaged Foods (CXS 1-1985).*
4 *Allergen cross-contact* as defined in *Code of Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).*
5 *FAO and WHO (2023). Risk assessment of food allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens (Sections 3.3.1 to 3.3.6). https://doi.org/10.4060/cc6081en*
6 Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). The amount of food should be established based a single eating occasion intake of the food preferably using the 50th percentile or mean of consumption data for the respective population(s) where available.

Commented [EFOAAADPA11]: Comment (368) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:42)
EFA insists on its central demand that PAL should be made mandatory. This is, among others, in line with one of the key recommendations of the FAO/WHO expert group report 3, published in June 2023. (https://www.who.int/publications/i/item/9789240072510 , pp 55).

Although the CCFL has not included this recommendation in the revised text, we continue to consider it critical to ensure the safety of consumers with food allergy.

In this respect, we would like to remind the Chairs that a voluntary PAL puts consumers with allergy at risk, as the lack of PAL is frequently misinterpreted as a lack of risk; while it is also often that PAL is not comprehensive.

Alternatively, in case mandatory PAL is no option for Codex, there must surely be an indication that risk assessment has been applied.

Commented [EFOAAADPA12]: Comment (369) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:45)
EFA would like to remind that a long-standing tolerance threshold has been established and implemented for coeliac disease at 20ppm for gluten, based on a Codex standard (CXS 118-1979). This makes it possible for food business operators to produce food that is "free from gluten".

However, coeliac-friendly products containing less than this amount of gluten may not always be safe for gluten-allergic individuals. Therefore, using PAL should not be restricted solely to meet the requirements for coeliac gluten-free claims.

In this light, EFA would highly recommend to either delete coeliac disease from this provision or to apply a separat ...

Commented [EFOAAADPA13]: Comment (370) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:46)
EFA reiterates that both quantitative and qualitative approaches can be taken for the assessment of risks from unintended allergen presence. However, quantitative risk assessments are the most effective method in determining whether a PAL statement should be used or not. We strongly encourage the Chairs to reflect this in the text, choosing one of the following options:

'...shall be based on the findings of a risk assessment, which shall include, where possible, quantitative risk assessment of unintended allergen presence',

...

Commented [EFOAAADPA14]: Comment (371) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:46)
EFA strongly holds that the decision to use PAL must be based on a risk assessment and the implementation of effective allergen control measures. This would include using allergen thresholds as one component of an overall effective allergen control plan.

Egg	2.0
Milk	2.0
Sesame	2.0
Hazelnut	3.0
Wheat	5.0
Fish	5.0
Buckwheat	10
Lupin	10
Soy	10
Crustacea	200

4.3.2 Where a reference dose is not established for a particular food allergen in the table to 4.3.1 above, regional or national authorities can establish a reference dose consistent with recognized principles[7] for the purposes of determining an action level.

4.4 PAL shall be accompanied by education/information programs to ensure understanding and appropriate use of PAL by consumers, health care providers and food business operators.

5. PRESENTATION OF PAL

5.1 Section 8.1.1, 8.1.2 and 8.1.3 and 8.2 of the General Standard for the Labelling of Prepackaged Foods (GSLPF) (CXS 1-1985) apply to PAL labelling.

5.2 PAL should appear as a separate statement directly under or in close proximity to the ingredient list (when present).

5.2.1 A PAL statement shall commence with the words 'May contain' (or equivalent words) and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF.

5.2.2 A PAL statement shall contrast distinctly from surrounding text such as through the same font type, style or colour used for declarations in accordance with section 8.3.1 of the GSLPF.

Commented [EFOAAADPA15]: Comment (372) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:47)
To comply with determining action levels based on the FAO/WHO expert advice, "can" should be replaced with "shall".

Commented [EFOAAADPA16]: Comment (373) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:47)
As per our previous recommendations, EFA reiterates that there needs to be an appropriate education strategy to cater for all food allergy patients, including those reacting to lower doses than ED05.

This is why it is so important to be able, in the near future, to provide allergen-free labels and educate consumers on interpreting PAL. EFA has also suggested that national authorities collaborate with food allergy patient associations to develop an education strategy that supports patients, consumers, healthcare providers, and food business operators.

Commented [EFOAAADPA17]: Comment (374) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:48)
As in our response to the 8.3.2.1 section of the consultation on the allergen-related provisions of the GSLPF, EFA strongly suggests to delete 'in close proximity'. Our concern is that it would be interpreted as 'on the other side of the box', for example, which would make it difficult to find for people with food allergy.

Therefore a precise indication where to find PAL is necessary. EFA strongly believes that PAL should appear as a separate statement directly under to the ingredient list.

Commented [EFOAAADPA18]: Comment (375) by European Federation of Allergy and Airways Diseases Patients' Associations (9 Oct 2024 10:49)
Linked again to our response in the 8.3.2.1 section of the consultation on the allergen-related provisions of GSLPF, EFA suggests the deletion of the '(or equivalent words)'. We believe that only one harmonized statement should be allowed to be used, as other options might create confusion and result in interpretation about the potential allergen content, which is not justified or helpful (e.g. "May contain traces" might lead someone to think that this means less allergen content than in "May contain" - which is not true)

[7] FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens. https://doi.org/10.4060/cc2946en.